EXHIBIT B2

In your opinion, is there a significant biomaterials difference between Prolift and Prolift+M?

MS. GERSTEL: Object to the form.

A. In terms of how it's designed and there being a permanent and an absorbable component to it , I would say yes, there's a significant difference.

Does that turn into a significant difference clinically? I'm not sure we know enough or have enough good studies to give a conclusion on that.

Q. Okay.

MR. RESTAINO: I'm going to have marked as next an article by Withagen, et al.

(Lind Exhibit 12, Withagen article Trocar-Guided Mesh Compared With Conventional Vaginal Repair in Recurrent Prolapse, was marked for identification, as of this date.)

BY MR. RESTAINO:

Q. Do you recall this article, sir?

Q. And under the mini section of "Previous Surgery" down towards the bottom you see sacrocolpopexy listed?

A. Yes.

Q. And do you see that there's a N of 6 under "Conventional" and 18 percent after that?

A. Yes.

Q. And then there's p-value of .01, correct?

A. Yes.

Q. Does that indicate to you there was a significantly significant larger number of patients that have previously had vaginal -- excuse me. Had sacrocolpopexy in the vaginal mesh group than in the conventional group?

A. Yes.

Q. Now, there's actually approximately almost three times as many women in the vaginal mesh group; is that correct?

A. Yes.

Q. And that's a source of bias, is

it not?

A. The study is randomized, which as we both know is best designed to minimize bias. Despite randomization, in this study you have more people in one group with a previous sacrocolpopexy than the other.

If you look down further, you have people, you have more patients with more than one previous surgery in the conventional group. So, you know, it goes both ways.

I think to me the key element for prolapse surgery is are the stages of prolapse similar, which they are in this study 'cause that's what you're starting with. If you have a stage 3 prolapse of a sacrocolpopexy, the bias that we're trying to discuss for a group that would have had more that would have had a previous support procedure would mean, well, she already has some support from the previous surgery, so that would lead towards possibly a better outcome for her having

BY MR. RESTAINO:

Q. If you would turn to page 14, they have a paragraph on 14 that starts off with: "We rated 18 studies."

Do you see that?

A. Which paragraph?

Q. I didn't write it down for myself. You want to hand it to me. I'll try to save you a little eye strain.

(Pause.)

It's the second paragraph under "Allocation."

A. Okay.

Q. (Reading) "We rated 18 studies that did not describe an adequate method of allocation concealment as at unclear risk in this domain, and we rated two studies as at high risk of bias, as they either did not use allocation concealment, in Tamanini 2014, or we suspected a high potential for bias (Withagen 2011.)"

Did I read that correctly?

A. Yes.

Q. And the Withagen 2011 is what we

were reading, correct?

A. Correct.

Q. Now, looking at the same page of that Cochrane analysis, you see they also have a paragraph titled "Selective Reporting"?

A. Yes.

Q. And there at the bottom the final sentence of that: "We rated one study as at high risk of selective reporting because the choice of primary outcome appeared to be inconsistent (Withagen 2011)."

Did I read that correctly?

A. Yes.

Q. And then if you look on the same page there's a section titled "Other Potential Sources of Bias." And then you see in the middle of that paragraph they write: "In Withagen 2011, women in the native tissue group had greater degree prolapse at point A posterior (Ap), point B posterior (Bp), and genital hiatus (GH) compared to the mesh group and prior

sacrocolpopexy was three times more frequent in the mesh group."

Did I read that correctly?

A. Yes.

Q. So these biases in Withagen are listed in the Maher systemic review that you describe as the highest evidence of scientific -- highest degree of scientific evidence; is that correct?

A. It is a -- it is in the category of the highest level, but we are microdissecting one analysis with Withagen. That is not the study in total.

Q. So you're selectively taking out sections of Withagen that support your opinions and you're disregarding that which is limited which is discussed in Cochrane?

MS. GERSTEL: Object to the form.

A. No. I am saying that if we are going to discuss Cochrane, you've given me four pages from Cochrane. So if we want to go into the details of that study and

Q. And if you look at the very bottom of that table, and I'm going to apologize to you, sir. I printed this out last night because I realized I had forgotten to print this out at home. The actual table is in color, and here at the inn they did not have a color printer. But you see at the bottom is the Withagen 2011? Do you see that, sir?

Now, I represent to you the very first column is green with a plus.

A. I'm sorry, tell me again.

Q. The first column which they title as "Random Consequence Generation (selection bias)."

A. Right.

Q. For Withagen it's green. It gets a plus.

A. Right.

Q. Now, next to it is "Allocation Concealment (selection bias)." That's red with negative.

A. Okay.

Q. After that "Blinding of

Participants and Personnel (performance bias)." That's red.

A. Got it.

Q. "Blinding of Outcome Assessment (detection bias)," and that's red.

A. Got it.

Q. Then comes a yellow with a question mark, and that column is "Incomplete Outcome Data (attrition bias)." And then the second to last is red "Selective Reporting (reporting bias)." And then the final column also red is "Other Biases."

So, in this table alone, aside from the colpopexy bias that you discuss, the Cochrane Review indicates the Withagen article has a minimum of five forms of bias, selection bias, performance bias, detection bias, reporting bias, other bias, which I will give you may include your argument regarding colpopexy.

Now, you indicated you read the Cochrane analysis in its entirety, correct?

A. Almost its entirety.

Q. Did you not see this section on Withagen?

A. I saw the section on Withagen.

Q. And is there any language in your expert report in those two paragraphs of Withagen indicating that this study does in fact contain five forms of bias?

A. No, there is not.

Q. Now, on page 8, sir, of your expert report, you discuss a section, an article Svabik, S-V-A-B-I-K.

Did I read that correctly?

A. Yes.

Q. And there Svabik and colleagues' trial compare Prolift Total to native tissue repair randomized 70 women into two treatment groups, correct?

A. Yes.

Q. And then the follow-up on page 9 of your expert report, they discuss the follow-up was conducted at three months and 12 months; is that correct?

A. Yes.

like we're on a different page. I think it's page 83. It's the third page of the document. It is page 83.

A. My top right says "Assessed."

Q. Yes, the first full sentence.

A. Yes.

Q. (Reading) "Ten of the originally included non-randomized studies were excluded as a result of short follow-up (less than 12 months.)"

Did I read that correctly?

A. Yep.

Q. So therefore, Schimpf, et al. would consider studies of less than 12 months as having been of short follow-up and actually excluded from their analysis; is that correct?

A. Yes, 12 months, not 24 months.

Q. Now, if you turn to the next page, you see "Outcomes and Interior Compartments"?

A. Yes.

Q. At the bottom of the paragraph they write: "20 studies compared

synthetic non-absorbable mesh and native tissue repair and 11 studies compared a graft or mesh or other graft material."

Did I read that correctly?

A. Yes.

Q. Then there's an appendix 3 link for that.

Did you pull the link and look at those 20 studies?

A. No.

Q. Do you know which mesh were included in those 20 studies?

A. No.

Q. Do you know how many of them consisted of Gynemesh or Prolift?

A. What fraction, no.

Q. And you had, when asked about the different mesh at the beginning of the deposition, you indicated it would be inappropriate to lump all polypropylene mesh together in one study, did you not?

MS. GERSTEL: Object to form.

A. Yes. However, most of the randomized control studies, if we can go

know if it was listed there?

A. I think the committee opinions are all listed on -- on the -- on the ACOG Web site and the AUGS Web site, but I don't specifically recall looking at it on the computer. I have the paper.

Q. And the paper itself was from the Journal of Obstetrics and Gynecology?

A. I would have to see the reference.

Q. Do you know that the Web page on ACOG regarding this committee opinion has been pulled down?

A. I'm not aware of that.

MR. RESTAINO: I'll go ahead and have the court reporter mark as next a printout of that page.

(Lind Exhibit 15, printout from ACOG Web site, was marked for identification, as of this date.)

A. When they pull them down, it's because they've updated them, and I want to make sure that pulling it down does not represent that they no longer support any

Reclassification of Mesh For Pelvic Organ Prolapse dated January 6, 2016.

(Lind Exhibit 17, ACOG Practice Advisory on the FDA's Reclassification of Mesh For Pelvic Organ Prolapse dated January 6, 2016, was marked for identification, as of this date.)

BY MR. RESTAINO:

Q. And you would agree that 2016, sir, is after 2011, correct?

A. Yes.

Q. And in this practice advisory dated January 6, 2016 on point number 1 they write: "The FDA reclassified these medical devices from Class 2, which generally includes moderate-risk devices, to Class 3, which generally includes high risk devices."

Did I read that correctly?

A. Yes.

Q. Now, while mentioning the ACOG committee opinion from 2011 in your expert report, you do not mention in your expert report that ACOG in 2016 notes that these

medical devices are now considered high risk devices, do you?

MS. GERSTEL: Object to form.

A. I have to look a little more through my statement because I think I do reference FDA notifications on devices.

Q. I'll represent to you that you do mention the 2008-2011 advisory, but nothing about --

A. Correct, I do not -- I do not mention the 2016 ACOG practice advisory that you have placed in front of me.

Q. Now, on page 13 of your Gynemesh expert report -- page 14 you have a paragraph where you state: "I have specifically discussed many of these in my analysis of the medical literature above."

Do you see that, sir? I think it's page 14.

A. Yes.

Q. (Reading) "With the exception of recurrent/failure rates and mesh exposure, significant differences in complication rates between mesh augmented and non-mesh

Q. I think so.

A. "Of those who were initially treated non-surgically"?

"Of the women who initially had in-office trimming"?

Q. Yes.

"Of the women who initially had in-office trimming of mesh, 73.3 percent eventually went to the operating room."

Did you see that, sir?

A. Yes.

Q. Now, again your expert report states the majority of exposures can be treated conservatively, whether expectantly or with topical estrogen cream, but these surgeons from these four medical centers found that 73.3 percent of these patients who undergo an in-office trimming ended up in the operating room, did they not?

A. The statements as they've written statistically and their results clearly are accurate. These are expert researchers and expert surgeons.

Q. About five or six lines down they start "First."

Do you see that?

A. Yes.

Q. (Reading) "First, approximately one-half of the women (49.3 percent) who sought treatment of a mesh related complication at a tertiary referral center actually underwent their index procedure at a facility other than that tertiary referral center."

And that's what you've been saying, correct?

A. Yes.

Q. (Reading) "This trend has been reported in other studies as well. Reference 12. This raises the potential concern that physicians who perform these mesh procedures may not be aware of the complications their patients experience and that these providers may be responsible for future mesh related complications with no awareness of the existing magnitude of the issue."

Did I read that correctly?

A. Yes.

Q. Now, the impetus for this entire line of questioning is you wrote in your expert report that mesh complications are typically mild and can be treated expectantly, mesh erosion can be treated expectantly and/or with estrogen cream, but you don't put in your expert report that there is a portion of women with the same complications that undergo very significant morbidity and surgical correction, correct?

MS. GERSTEL: Object to form.

A. I think I do indicate in my report that people do require surgery to correct this. How detailed I get into on how invasive the repairs are is not detailed as specifically as the line of questioning here. That's fair.

Q. Do you state for the judge the percentage, almost 50 percent that have to undergo a mesh excision in this situation?

MS. GERSTEL: Object to the

form.

A. I strongly disagree with the 46 percent which you're quoting from this article, as I've stated previously, is a cross-sectional collection of four case series lumped together referred to four of the top people in the nation and does not represent the -- any of the percentages of requiring mesh complete removals as based on the stronger studies, randomized studies, and from a statistical design standpoint, to be quoting these as the risk of total removal rate of 46 percent is dismissing everything that we have both learned in terms of statistical design and what is legitimate to state as an overall risk.

Q. But it is data, correct?

A. It is data of the worst cases sent to the surgeons who take the cases that no one else can take. That's biased data.

MS. GERSTEL: The time is at two hours.